

REMARKS

Claims 30, 35, 37, 38, 51, 54, 69, 70, and 73-82 are currently pending in the present application, including independent claim 35. Independent claim 35 is directed to a wiper comprising a nonwoven fabric and a sanitizing formulation applied to the nonwoven fabric in an amount from about 150% to about 600% of the dry weight of the wiper. The sanitizing formulation consisting essentially of one or more nonionic surfactants, between about 0.01% by weight to about 0.4% by weight of at least one benzalkonium halide, between about 0.01% to about 0.5 % by weight of ethylenediaminetetraacetic acid and/or salts thereof, and a solvent. The sanitizing formulation has a pH of greater than about 8 and is configured so that it is released from the nonwoven fabric as a solution during use of the wiper in food service applications. The benzalkonium halide being present within the released solution in an amount less than about 2000 parts per million of the released solution, and the wiper exhibits a Kill Efficiency Ratio for *E. Coli*, *S. Aureus*, or both of at least about 100.

The Office Action rejected independent claim 35 under 35 U.S.C. §103 in view of Harrison, et al. (U.S. Pat. No. 6,667,289) in combination with Sherry, et al. (U.S. Pat. No. 6,716,805). However, Applicants respectfully submit that presently amended claim 35 is patentable over Harrison, et al. in any combination.

Harrison, et al. is directed to an aqueous cleaning composition useful in removing dirt and grime from surfaces, such as glazed ceramic tiles, polished metals, enameled metal surfaces, and glazed porcelain. The aqueous cleaning composition of Harrison, et al. contains the following constituents: (A) quaternary ammonium surfactant compound having germicidal properties; (B) surfactant system which includes at least

one amine oxide surfactant, and at least one further surfactant selected from carboxylates and N-acyl amino acid surfactants, especially sarcosinates; (C) solvent system containing an alkylene glycol ether solvent further with a C₁-C₆ alcohol, especially where the C₁-C₆ alcohol is isopropanol; (D) alkalizing agent such as an alkanolamide, especially an alkylamine; and (E) water. (Col. 1, lines 40-54).

Harrison, et al. primarily focuses on providing its cleaning/disinfecting composition as a ready to use product in a manually operated spray dispensing container so that its composition is ideally suited for use in a consumer "spray and wipe" application. (See e.g., col. 7, line 52 – col. 8, line 2; col. 11, line 56 – col. 12, line 2, and Examples 1-4). Only at col. 12, lines 29-65, does Harrison, et al. even cursorily introduce the concept of absorbing its cleaning/disinfecting composition onto a wipe to form a saturated wipe for use on an "as-needed" basis.

However, independent claim 35 requires that the benzalkonium halide is present *within a released solution* in an amount less than about 2000 parts per million of the released solution, while at the same time attaining a high log reduction for *E. coli*, *S. Aureus*, or both. *Nowhere* does Harrison, et al. recognize that it may be beneficial to know the *contents* of the solution the wiper is releasing—more particularly, to *know, and to control*, the benzalkonium halide content within that released solution.

Harrison, et al. expressly requires the use of a carboxylate or N-acyl amino acid surfactant, which are both anionic surfactants. In stark contrast, the sanitizing formulation of independent claim 35 specifically excludes the presence of an anionic surfactant ("sanitizing formulation consisting essentially of one or more nonionic surfactants"). The presence of an anionic surfactant can adversely affect the

effectiveness of the benzalkonium halide, of which the benzalkonium cation is the effective antimicrobial agent. For example, an anionic surfactant can ionically bond to the benzalkonium cation and reduce the amount of benzalkonium cations available to kill the microbes. In some instances, the presence of an anionic surfactant could even precipitate the benzalkonium cation from the sanitizing formulation. Applicants submit that exclusion of the anionic surfactants required by Harrison, et al. is in direct contrast with Harrison, et al.'s express teachings.

Thus, contrary to the assertions in the Office Action, Harrison, et al. does not teach a composition consisting essentially of one or more nonionic surfactant, at least one benzalkonium halide, ethylenediaminetetraacetic acid or its salt, and a solvent. Applicants respectfully submit that one of ordinary skill in the art would not *exclude* an expressly required component – i.e., the “at least one further surfactant selected from carboxylates and N-acyl amino acid surfactants” – of the formulation disclosed by Harrison, et al. Thus, Applicants respectfully submit that independent claim 35 is allowable over Harrison, et al. in any combination.

Furthermore, Harrison, et al. also fails to teach a solution having a pH value of greater than about 8. Harrison, et al. does disclose the use of an option pH adjusting agent or buffer composition. (Col. 8, line 55 – col. 9, line 18). However, Harrison, et al. fails to teach or suggest a pH range for their compositions. In fact, Harrison, et al. teaches that an effective amount of an organic acid (e.g., citric acid) may be used to adjust and maintain the pH of their compositions. Presumably, an organic acid would lower the pH of Harrison, et al.'s composition. Thus, Applicants respectfully submit that

Harrison, et al. actually teaches away from a solution having a pH of greater than about 8, such as required by independent claim 35.

While Applicants continue to assert that the above-mentioned aspects of independent claim 35 are not taught by Harrison, et al., claim 35 requires that the wiper exhibit a "Kill Efficiency Ratio" ("KER") of at least about 100. KER is defined as the number of bacteria killed divided by the amount of antimicrobial agent (ppm) added to the sanitizing formulation. (Appl. p. 33). This ratio may vary greatly based on the selected combination of features (e.g., the ingredients of the sanitizing formulation, relative amounts, add-on levels, wiper materials, etc.). To best illustrate this point, reference may be made to the Examples set forth in the present application. More specifically, listed below in Table 1 are the KER values for Formulations 30-37 of Example 2 of the present application:

Table 1: Properties & KER Values (*S. Aureus*) for Formulations 30-37:

Component	30	31	32	33	34	35	36	37
Benzalkonium chloride	981 ppm	763 ppm	601 ppm	415 ppm	1946 ppm	1993 ppm	1997 ppm	1981 ppm
EDTA	1.00 wt. %	1.00 wt. %	1.00 wt. %	1.00 wt. %	0.45 wt. %	-	0.15 wt. %	0.15 wt. %
Nonionic Surfactant	0.05 wt. %	0.10 wt. %	0.20 wt. %	0.50 wt. %	-	-	-	-
Ethanol	-	-	-	-	10.0 wt. %	10.0 wt. %	10.0 wt. %	10.0 wt. %
Methyl paraben	-	-	-	-	0.10 wt. %	0.10 wt. %	0.10 wt. %	0.10 wt. %
Propyl paraben	-	-	-	-	0.04 wt. %	0.04 wt. %	0.04 wt. %	0.04 wt. %
Sodium meta silicate	-	-	-	-	-	1.50 wt. %	0.90 wt. %	-
Water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
pH	11.4	11.4	11.4	11.4	9.1	9.1	9.2	9.1
KER	102	131	166	241	3	3	3	3

As indicated, variations in the components and concentrations of the sanitizing formulation may result in substantial changes in the KER values for *S. Aureus*. For instance, Formulations 34-37, which lacked a nonionic surfactant, had KER values of only 3. To the contrary, Formulations 30-33 had KER values from 102 to 241. Moreover, variations in the concentration of the benzalkonium halide and nonionic surfactant resulted in substantial changes in the KER values for the Formulations 30-33. Notably, such high KER values were achieved for released solutions containing a relatively low amount of the benzalkonium halide (e.g., from 380 to 418 ppm for Formulations 30-33).

Harrison, et al. simply fails to disclose or suggest a wiper that meets all of the limitations of independent claim 35, including the composition of the sanitizing formulation and the required Kill Efficiency Ratio. To the contrary, Harrison, et al. provides only enough information to tell one of ordinary skill in the art (1) that Harrison, et al.'s cleaning compositions "can also be applied to a hard surface by using a wet wipe," and (2) that the compositions can be "absorbed onto the wipe to form a saturated wipe." *Nowhere* does Harrison, et al. recognize that it may be beneficial to know the *contents* of the solution the wiper is releasing—more particularly, to *know, and to balance*, the benzalkonium halide content and the resulting antimicrobial efficacy. More specifically, through optimization of antimicrobial efficacy, smaller concentrations of antimicrobial agent may be utilized, which in turn leads to a higher Kill Efficiency Ratio. This is especially important in food service applications where it is desired to minimize the likelihood that the antimicrobial agent will become present in large amounts in food that later contacts the wiped surface. (Appl., pp. 12-13).

In an attempt to overcome these deficiencies of Harrison, et al., the Office Action refers to Sherry, et al. and states that it would have been obvious to use their “wetness of 1-5 grams of solution per gram of wipe”. However, even if combined, the combination still fails to disclose the particularly claimed sanitizing formulation of independent claim 35. As such, Applicants again assert that independent claim 35 is patentable over Harrison, et al. in any combination.

Additionally, the Office Action rejected independent claim 35 under § 103 in view of Sherry, et al. in combination with Harrison, et al. However, Applicants respectfully submit that presently amended claim 35 is patentable over Sherry, et al. in any combination.

Sherry, et al. is directed to hard surface cleaning compositions and their use with absorbent pads. Sherry, et al. describes several different types of compositions, specifically (a) “daily shower” compositions, (b) glass cleaner compositions, and (c) general purpose and conventional floor cleaning compositions. (See, respectively, col. 21, line 45 – col. 23, line 29; col. 23, line 30 – col. 24, line 36; and col. 24, line 37 – col. 25, line 67). Also, Sherry, et al. teaches that the glass cleaner compositions or the general purpose and conventional floor cleaning compositions (of b and c above) can be used in a premoistened wipe. (Col. 26, lines 1-6).

The Office Action states refers to the statement on col. 9, lines 29-32 of Sherry, et al. as not requiring the hydrophilic polymer: “When the polymer is not present in the compositions herein, the compositions will normally have one of the preferred surfactants present.” The Office Action concludes that this statement allows for the

polymer to be omitted from their formulation. However, the Office Action's conclusion does not take into account the entire teachings of Sherry, et al.

While some embodiments may not have the hydrophilic polymer, Sherry, et al. teaches in the "Premoistened Wipes for Floors, Counters, and/or Walls" section from col. 35, line 56 – col. 39, line 20 that the cleaning composition includes a hydrophilic polymer and an effective amount of a primary detergent surfactant, along with several optional ingredients described in compositions "b" and "c". (Col. 35, lines 58-60). Thus, the embodiments of Sherry, et al. that are directed to a wet wipe – as required in any attempt to somehow equate to the subject matter of independent 35 of the present application – expressly and unequivocally require the presence of the hydrophilic polymer.

In fact, Sherry, et al. teaches that the hydrophilic polymer is "essential" to the composition in order to improve the hydrophilicity of the surface being treated. (Col. 5, lines 45-48). In this premoistened wipe embodiment, an anti-microbial system can be included. The anti-microbial system can include the use of quaternary ammonium salts such as dimethyl benzyl ammonium chlorides. (Col. 36, lines 57-61 and col. 37, lines 22-32). Sherry, et al. further teaches that an "important" benefit of the wet wipes they disclose is that fact that they "allow for residual disinfectancy benefits." (Col. 37, lines 33-39). By residual disinfectancy, Sherry, et al. means that the residual antimicrobial actives delivered by the wet wipe onto the hard surface at least about 99.9% cidal against bacteria and other microorganisms for a period of from about 8 to about 72 hours, more preferably from about 12 to about 48 hours, most preferably at least about 24 hours. Sherry, et al. teaches that the residual properties result from a combination of

low vapor pressure and high cidal efficacy of the antimicrobial actives associated with the compositions of the present invention. (Col. 37, lines 39-56).

However, Sherry, et al. fails to teach or suggest the sanitizing formulation of independent claim 35. Nowhere does Sherry, et al. teach or even suggest a sanitizing formulation consisting essentially of one or more nonionic surfactants, between about 0.01% by weight to about 0.4% by weight of at least one benzalkonium halide, between about 0.01% to about 0.5 % by weight of ethylenediaminetetraacetic acid and/or salts thereof, and a solvent, as required by independent claim 35.

In fact, Sherry, et al. teaches away from the wipe of independent claim 35, since the inclusion of a hydrophilic polymer is excluded from the sanitizing formulation of claim 35. Sherry, et al. specifically teaches that the hydrophilic polymer is "essential" to the composition in order to improve the hydrophilicity of the surface being treated. (Col. 5, lines 46-47). Thus, no rationale exists for one of ordinary skill in the art to omit such an "essential" ingredient in an attempt to somehow modify the formulation of Sherry, et al.

In fact, one of ordinary skill in the art would recognize that the omission of the "essential" hydrophilic polymer would destroy the intended purpose of the solution of Sherry, et al. Sherry, et al. specifically teaches that their premoistened wipes having antimicrobial actives provide residual antimicrobial actives delivered by the wet wipe onto the hard surface at least about 99.9% cidal against bacteria and other microorganisms for a period of from about 8 to about 72 hours, which is primarily due to the hydrophilic polymer included in the solution "as is prolongs the sheeting and cleaning benefits." (Col. 5, lines 64-65 and col. 37, lines 30-43). This "residual

antimicrobial actives" is the type of result that the wipers of independent claims 27 and 35 are designed to avoid by having the benzalkonium halide present within the released solution in an amount less than about 2000 parts per million of the released solution. Thus, the wiper of claim 35 may minimize the "residual antimicrobial actives," which is important when the wiper is used in food service applications. For instance, the present application teaches that solutions released by wipers in the food service environments are often required to contain a relatively small amount of the antimicrobial agent. For example, Title 21, Section 178.1010 of the United States Code of Federal Regulations sets forth various requirements for use of sanitizing solutions used on food-processing equipment, utensils, and other food-contact articles. (Pg. 1, lines 15-21).

Applicants respectfully assert that excluding the "essential" and expressly required hydrophilic polymer from the wet wipe of Sherry, et al. would effectively destroy its intended and stated purpose. Thus, one of ordinary skill in the art would not somehow modify the teachings of Sherry, et al. in the manner suggested by the Office Action.

Applicants also respectfully submit that for at least the reasons indicated above relating to corresponding independent claims, the pending dependent claims patentably define over the references cited. However, Applicants also note that the patentability of the dependent claims certainly does not hinge on the patentability of independent claims. In particular, it is believed that some or all of these claims may possess features that are independently patentable, regardless of the patentability of the independent claims.

Applicants respectfully submit that the present application is in complete condition for allowance, and therefore respectfully request favorable action and reconsideration of rejections of the Office Action with regard to the above remarks. However, any further questions or concerns, the Examiner is invited and encouraged to contact the undersigned. Please charge any deficiencies or credit any overpayments required by this Response to Deposit Account No. 04-1403.

Respectfully requested,
DORITY & MANNING, P.A.

Date: May 4, 2010

A handwritten signature in black ink, appearing to read 'Alan R. Marshall', is written over a horizontal line.

Alan R. Marshall
Registration No. 56,405
P.O. Box 1449
Greenville, SC 29602-1449
Phone: (864) 271-1592
Facsimile: (864) 233-7342